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IN OPEN COURT
MAY - 7
CLERK, U.S. DISTRICT COURT
ALEXANDRIA, VIRGINIA

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

UNITED STATES OF AMERICA

v.

TC MEDICAL GROUP,
Defendant

Criminal No. 1:14-cr-397-1

Hon. Anthony J. Trenga

STATEMENT OF FACTS

The United States and the defendant, TC MEDICAL GROUP, agree that the following facts are true and correct, and that had this matter proceeded to trial, the United States would have proven them beyond a reasonable doubt with admissible and credible evidence:

1. Beginning in at least April 2011, and continuing until December 2014, in the Eastern District of Virginia and elsewhere, the defendant, TC MEDICAL GROUP, together with other co-conspirators, including TZVI LEXIER, DAVID E. BURKE, a/k/a "David Johnson," HANOCH DAVID STEIN, a/k/a "Albert Simmins," SHLOMO RABI, a/k/a/ "David Anderson," ASAF AKIVA IBRAHIMIAN, a/k/a "Adam Darius," and REUVEN MIRLIS, a/k/a "Daniel Mirl," and other individuals including co-conspirators based in Canada, including R.L. and S.R., co-conspirators in Germany, including C.G., and co-conspirators in the United States, including A.T. in Baltimore, Maryland; R.R. and M.R. in Lakewood, New Jersey; S.M. and E.M. in Edison, New Jersey; and A.B. in Boynton Beach, Florida, and with intent to defraud and mislead, engaged in a conspiracy to smuggle into and distribute within the United States, including within the Eastern District of Virginia, misbranded prescription drugs and devices.

2. The misbranded and non-FDA approved prescription drugs and devices smuggled and sold in the United States by the conspiracy included the following:

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Product	Use
Aclasta	Injectable drug used to treat osteoporosis (bone decay). Not FDA-approved for use in the United States. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Actemra	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation). Subject to FDA black-box warning: "[I]ncreased risk for developing serious infections that may lead to hospitalization or death." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light and moisture.
Artzal	Injectable device used to treat osteoarthritis (joint pain). Not FDA-approved for use in the United States.
Bonviva	Injectable infusion drug used to treat of osteoporosis (bone decay). Not FDA-approved for use in the United States.
Botox	Injectable prescription drug used to treat bladder disorders, chronic migraines, muscle spasms, and abnormal head positions. Subject to FDA black-box warning: "Swallowing and breathing difficulties can be life threatening and there have been reports of death." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Botox Cosmetic	Injectable prescription drug used to treat forehead wrinkles. Subject to FDA black-box warning: "Swallowing and breathing difficulties can be life threatening and there have been reports of death." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Dysport	Injectable prescription drug used to treat abnormal head positions and forehead wrinkles. Subject to FDA black-box warning: "Swallowing and breathing difficulties can be life threatening and there have been reports of death." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light.
Euflexxa	Injectable Class III prescription device used to treat osteoarthritis (joint pain). Must be kept away from light.
Hyalgan	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Juvederm	Injectable Class III prescription device used to treat facial wrinkles and folds. Juvederm 2, Juvederm 3, and Juvederm 4 are not FDA-approved for use in the United States.
Lucentis	Injectable prescription drug used to treat macular degeneration of the eye. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light.
Mabthera	Injectable prescription chemotherapy drug not FDA-aproved for use in the United States. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from direct sunlight or shaking.
Macrolane	Injectable Class III device used for body contouring. Not FDA-approved for use in the United States.
Orencia	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation). Cold-chain product must be stored at temperatures from

	2°C-8°C (36°F-46°F), and away from light and freezing.
Orthovisc	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Prolia	Injectable prescription drug used to treat osteoporosis (bone decay). Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light, heat, and vigorous shaking.
Radiesse	Injectable Class III prescription device used to treat facial wrinkles and folds.
Remicade	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation), bowel inflammation, skeletal inflammation, skin inflammation, and other conditions. Subject to FDA black-box warning: "Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Restylane	Injectable Class III prescription device used to treat facial wrinkles and folds, lip-filler.
Supartz	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Synvisc	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Zometa	Injectable prescription drug used to treat complications associated with cancer.

3. Specifically, members of the conspiracy did knowingly and intentionally combine, conspire, confederate, and agree, with each other and with other persons, to: (a) defraud the United States and its agencies by: impeding, impairing, and defeating the lawful functions of the Food and Drug Administration ("FDA") to protect the health and safety of the public by ensuring that prescription drugs and devices distributed in the United States were safe and effective from the time of manufacturing to the delivery to the entity that sold or dispensed the product to the ultimate consumer or patient; and impeding, impairing, and defeating the lawful functions of Customs and Border Protection ("CBP") and Immigration and Customs Enforcement—Homeland Security Investigations ("ICE-HSI") to protect the public health and safety by governing the importation into the United States of goods and merchandise, including

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drugs and devices, through deceitful and dishonest means; (b) fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law; (c) introduce into interstate commerce misbranded prescription drugs and devices; and (d) knowingly engage in the wholesale distribution in interstate commerce of prescription drugs in the United States, including to the Commonwealth of Virginia, without being licensed to do so.

4. The misbranded and non-FDA approved prescription drugs and devices smuggled and sold by members of the conspiracy included orthopedic injections, rheumatology infusions, cosmetic devices, optomology products, and oncology drugs, which were often subject to stringent storage and handling requirements (such as cold-chain products required to be kept at a consistently low temperature for their safe use), and FDA "black box warnings" which is the strongest warning the FDA requires. The FDA requires "black box warnings" when a drug carries a significant risk of serious or life-threatening adverse effects.

5. The prescription drugs and devices smuggled and distributed by members of the conspiracy were misbranded because they failed to bear adequate directions for use in that they, among other things, (a) were not in the possession of a person, or his agents or employees, who was regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices; (b) failed to bear a label that contained the required language limiting their use to prescription only and for prescription drugs; (c) failed to bear the FDA-approved labeling and/or at any time before dispensing its label failed to bear, at a minimum, the "Rx only" symbol. The drugs and devices were also misbranded in some cases because the required labeling failed to

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bear information required under the Food, Drug, and Cosmetic Act (FDCA) in the English language. 21 U.S.C. § 352(f)(1).

6. In addition, neither defendant SB MEDICAL INC., nor defendant TC MEDICAL GROUP, nor any of their employees or co-conspirators were licensed wholesale distributors permitted to sell prescription drugs within the United States and in the Commonwealth of Virginia, and so were not regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States. Neither TC MEDICAL GROUP nor its employees or co-conspirators adhered to appropriate storage and handling, record-keeping, and reporting requirements as would be required of lawful and licensed wholesalers in the United States. In particular:

a. Facilities used by members of the conspiracy for the storage and handling of prescription drugs and devices consisted of unregistered commercial mailboxes at United Parcel Service ("UPS") and other commercial vendors, residential backyards and porches, basement rooms, garages, kitchen fridges and freezers, and personal residences which did not have adequate lighting, ventilation, temperature, humidity, and security as required for the safe handling and storage of prescription drugs and devices. Members of the conspiracy—who did not have any formal training or experience in handling prescription drugs and devices—did not properly quarantine damaged, deteriorated, misbranded, or adulterated prescription drugs and in some cases caused them to be shipped to United States doctors and medical practices.

b. Shipping methods used by members of the conspiracy were designed to evade law enforcement detection, and so often took weeks to arrive in the United States from abroad. Instead of using dry ice or other means of appropriately packing prescription drugs and devices and shipping them by overnight mail, members of the conspiracy often used ice packs

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and cooling packs, Styrofoam boxes, and other picnic cold packs from Walmart or other stores for shipment over longer periods of time, and often failed to keep cold chain prescription drugs at the required temperatures altogether. As a result, certain FDA-regulated products required to be kept at low and specific temperatures routinely arrived warm, wet, or otherwise damaged.

c. Members of the conspiracy, not being regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices in the United States, did not keep the required records and reports as required of lawful and licensed wholesalers in the United States.

7. The defendant agrees that SB MEDICAL, INC. and TC MEDICAL GROUP, together with members of the conspiracy, caused misbranded and non-FDA approved prescription drugs and devices to be smuggled into the United States and distributed as follows:

a. Beginning in or around April 2011, members of the conspiracy purchased from co-conspiring foreign suppliers prescription drugs and devices manufactured and labeled for use in foreign countries, including the Republic of Turkey, Canada, France, Italy, the United Kingdom, and other countries, and caused them to be shipped into the United States. These prescription drugs and devices were forwarded to the United States through the United Kingdom to doctors and medical practices in the United States, or alternatively to locations including the personal residences and mailboxes of co-conspiring individual drop shippers in the United States.

b. Drop shippers in the United States regularly received packages of prescription drugs and devices from abroad, removed labels and other indicia showing that they had been imported from abroad, repacked the orders, and re-shipped them to doctors and medical practices throughout the United States, including to the Eastern District of Virginia, to give the false impression that the drugs were being distributed domestically and legally.

c. To impede, impair, and defeat the lawful functions of the FDA, CBP, and ICE-HSI, the defendants, together with other co-conspirators, engaged in deceitful and dishonest means, including: (i) breaking up large shipments of prescription drugs and devices into smaller separate packages to be sent into the United States to multiple locations, under multiple names, over multiple days, to be consolidated upon arrival after evading border detection; (ii) shipping packages via Royal Mail and Parcelforce Worldwide, which—because they were United Kingdom-based services—allowed packages to be delivered through the United States Postal Service with less scrutiny than would be applied to packages arriving from other countries; (iii) including on customs forms false or misleading statements about the package contents and value, and addressing packages to co-conspirators under false names and/or titles; (iv) frequently mishandling prescription drugs subject to strict temperature requirements by failing to keep them at a consistent temperature during shipping and storage as required for the drug's safe and effective use; and (v) failing to keep and provide the appropriate pedigree records to prove or track the proper shipping, storage, and transaction history of prescription drugs through the supply chain.

8. All of the criminal actions, described herein, were committed by officers, employees, and agents of SB MEDICAL, INC. and TC MEDICAL GROUP, acting within the course and scope of the employment or agency given to them by SB MEDICAL, INC. and TC MEDICAL GROUP, and was committed with the intent to benefit SB MEDICAL, INC. and TC MEDICAL GROUP. Each of the criminal actions, described herein, related directly to the

general duties that the SB MEDICAL, INC. or TC MEDICAL GROUP officer, employee, or agent was expected to perform by those companies.

9. The illegal actions that officers, employees, and agents of SB MEDICAL, INC. and TC MEDICAL GROUP took on their behalf and for their benefit include, but are not limited to, the following:

a. TZVI LEXIER, a citizen of Canada, among other things, was a principal of TC MEDICAL GROUP and SB MEDICAL, INC. LEXIER's duties at TC MEDICAL GROUP and SB MEDICAL, INC. included obtaining and coordinating the supply of drugs and devices from foreign countries ultimately intended for the illegal importation into and sale inside the United States, and managing the finances and commission payments to co-conspirator sales representatives and drop shippers in the United States on behalf of TC MEDICAL GROUP and SB MEDICAL INC. LEXIER personally supervised the companies' "drop-shippers" in the United States, including HANOCH DAVID STEIN, and ensured that they took sufficient steps to avoid detection from law enforcement, including obtaining locations in which to receive shipments of misbranded drugs under false names.

b. DAVID E. BURKE's role was to oversee the day-to-day operations of TC MEDICAL GROUP and SB MEDICAL INC. Among other things, and working with co- TZVI LEXIER and others, BURKE supervised and managed co-conspirator sales representatives and drop shippers in the United States, tracked and coordinated shipments from overseas into the United States, called United States-based customers to sell prescription drugs and devices from abroad, and engaged in the illegal importation and sales of misbranded drugs and devices. BURKE used the false name "David Johnson" in connection with his activities, and instructed SB MEDICAL, INC and TC MEDICAL GROUP'S sales staff as to how to deceive the

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companies' clients into believing that the companies were based in the United States and were selling FDA-approved products.

c. HANOCH DAVID STEIN served as an individual drop shipper in the Baltimore, Maryland, area. At the direction of TZVI LEXIER and DAVID BURKE, STEIN received, repacked, and re-shipped misbranded prescription drugs and devices to customers throughout the United States to give the false impression that TC MEDICAL GROUP and SB MEDICAL INC. were based in the United States. STEIN often used the false name "Albert Simmins" or "Albert Simmons" in connection with his activities.

d. SHLOMO RABI, ASAF AKIVA IBRAHIMIAN and REUVEN MIRLIS were sales representatives for TC MEDICAL GROUP and SB MEDICAL INC. responsible for selling misbranded prescription drugs and devices to customers in the United States, including in the Eastern District of Virginia. At the direction of TZVI LEXIER and DAVID BURKE, these individuals used deception sales practices designed to deceive the companies' clients into believing that the companies were based in the United States and were selling FDA-approved products.

10. In addition, members of the conspiracy regularly communicated with each other via email about the foreign acquisition, illegal importation, sale of misbranded prescription drugs and devices in the United States, and the transfer of proceeds from the United States back to Canada. For example:

a. On May 31, 2011, HANOCH DAVID STEIN informed TZVI LEXIER and DAVID E. BURKE: "customers have been complaining about the Botox arriving warm. Storing and purchasing dry ice is complicated, also it freezes the good... Up until now I have been using smaller coolers (with a thinner wall) and smaller ice packs (to save on shipping)."

b. On December 12, 2011, HANOCH DAVID STEIN informed TZVI LEXIER that: "3 Turkish from [a doctor] FYI They were sent in an envelope (warm) They are taped together. Let me know if you can sell them and who I should send them to." A co-conspirator responded: "david, please put them in the fridge - we are selling them as normal."

c. On April 10, 2012, DAVID E. BURKE falsely represented to a medical practice in McLean, Virginia, in the Eastern District of Virginia that: "Frozen products such as Botox are shipped only by overnight Priority FedEx (medical/frozen special handling) on several kilograms of dry ice... All products are transported and stored in climate controlled environments. Frozen products such, as Botox, are maintained in a cold storage facility at all times and our partner pharmacies are fully licensed t o dispense & ship medication."

d. On September 10, 2012, DAVID E. BURKE, in an email copying TZVI LEXIER, instructed a drop shipper in the United States that: "The procedure should be as follows: 1. Box comes to you. 2. You open and count the products in each box. 3. You then send an email to accounting@tcmedicalgroup.com and report how many boxes came in and what was in each box. (Example: hello, I received 5 boxes today, box 1 was 20 synvisc, box 2 was 30 euflexxa, box3 was 10 orthovisc etc etc...) 4. You then pack all the stuff into one box and make sure to use packing tape, as well please handle these products with care and then head over to the local shop and ship them to Baltimore."

e. On January 15, 2013, TZVI LEXIER forwarded to a co-conspirator an email from DAVID E. BURKE with the headline: "FDA takes action against illegal drug importation of Botox" which noted: "Importation without FDA approval is illegal. According to the United States Federal Food, Drug, and Cosmetic Act (FDCA), unauthorized drugs that are imported are considered unapproved, misbranded, and adulterated (21 U.S.C. 331)."

f. On May 28, 2013, a drop shipper in the United States wrote to DAVID E. BURKE: "Don't know if this is a problem but one of the boxes of orencia was wet when I took it out of cooler today." A co-conspirator responded: "please Refrigerate the damaged box of Orencia, but put it separately from the other Orencia. We have one client or two that doesn't mind taking damaged boxes. When we receive an order from them we will send the damaged Orencia...."

g. On or about July 28, 2013, DAVID E. BURKE emailed co-conspirators, including TZVI LEXIER, that: "I do not want us sending lots of Botox into the us at one time."

h. On August 14, 2013, DAVID E. BURKE emailed a co-conspirator noting: "invoices are mislabeled in order to get it into the country. You stand to lose a lot here if the s--- hits the fan." BURKE then emailed TZVI LEXIER and a co-conspirator that: "I want to start royal mailing all fillers going forward... Turkish Botox going forward is probably not the best option to be utilizing... Dysport... we only need maximum 100 a month....this can be broken down to small shipments of 20 over a 4 week period... I also recommended to all guys here to stay low for now... tzvi agrees with this."

i. On January 3, 2014, DAVID E. BURKE emailed TZVI LEXIER and another co-conspirator an email with subject line "Oncology products" and noted: "Please let me know what products we can get our hands on... English Packaging will be an easier and safer sale."

j. On December 16, 2014, DAVID E. BURKE texted TZVI LEXIER that:

> My point is the way you talk about the guy who helped build your business the MOST instrumental part of this company from day f--king one... I have given my blood, sweat and tears for this company from day f--king one. I'm the best thing that ever happened to you... No one will ever be able to do what I did for you. It isn't just the cosmetics... it's the infrastructure I'm which we rely on daily to this

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> day. The FDA agents that have had there attention drawn elsewhere... the clients that would have left in all departments had I not got involved you and chris just saw the money... not what it took to make sure it stayed in all our pockets. You underestimate me Tzvi.

11. In addition, TC MEDICAL GROUP, together with co-conspirators, moved the proceeds from the sale of misbranded prescription drugs and devices which had been imported contrary to law from the United States to bank accounts in Canada. To do so, the defendant used credit card payment systems and processors to transfer proceeds from the United States to Canada. The defendant also employed co-conspirator drop shippers based in the United States to receive payment checks by mail and forwarded them to Canada to be deposited into bank accounts, all to give the false impression to customers that the defendant operated legally in the United States. Once the funds were in the bank account of SB MEDICAL INC., the conspirators caused further financial transactions to be made in furtherance of the conspiracy, including payments to foreign co-conspirator suppliers of misbranded prescription drugs, and payments to the companies' officers, employees, and agents, including TZVI LEXIER, DAVID BURKE, and others.

12. The statement of facts includes those facts necessary to support the defendant's guilty plea. It does not include each and every fact known to the defendant or to the government and it is not intended to be a full enumeration of all of the facts surrounding the defendant's case.

13. The actions of the defendant, as recounted above, were in all respects knowing, voluntary, and intentional, and were not committed by mistake, accident or other innocent reason.

14. The defendant waives any rights under Fed. R. Crim. P. 11(f), Fed. R. Evid. 410, the United States Constitution, and any federal statute or rule in objecting to the admissibility of the Statement of Facts in any such proceeding.

Dana J. Boente
United States Attorney

By: ______________________
Alexander T.H. Nguyen
Kellen S. Dwyer
Jay V. Prabhu
Assistant United States Attorneys

Defendant's Signature: After consulting with counsel, I hereby stipulate that the above Statement of Facts is true and accurate and that had the matter proceeded to trial, the United States would have proved the same beyond a reasonable doubt.

Date: MAY 05, 2015

Dr. Reuven Lexier, authorized representative of
TC MEDICAL GROUP
Defendant

Defense Counsel Signature: I am the attorney for TC MEDICAL GROUP. I have carefully reviewed the above Statement of Facts with Dr. Reuven Lexier, an authorized representative of TC MEDICAL GROUP. To my knowledge, his decision, on behalf of TC MEDICAL GROUP, to stipulate to these facts is an informed and voluntary one.

Date: 7 May, 2015

Jeff Ifrah, Esq.
Counsel for the Defendant